

Richard Schnizer, Ph. D

1635

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to 2/25/04.
2. ☒ The allowed claim(s) is/are 1-4, 6-8, 10, 28, 30, 31 and 39-49.
3. ☒ The drawings filed on 2/5/99 are accepted by the Examiner.
4. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) ☐ All b) ☐ Some* c) ☐ None of the:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).
 - * Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

5. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
 6. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
 - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
 - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
 - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
7. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. ☐ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3. ☒ Information Disclosure Statements (PTO-1449 or PTO/SB/08),
Paper No./Mail Date 11-9-04
4. ☐ Examiner's Comment Regarding Requirement for Deposit
of Biological Material
5. ☐ Notice of Informal Patent Application (PTO-152)
6. ☐ Interview Summary (PTO-413),
Paper No./Mail Date _____.
7. ☒ Examiner's Amendment/Comment
8. ☒ Examiner's Statement of Reasons for Allowance
9. ☐ Other _____.

EXAMINER'S AMENDMENT

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Connie Wong on 4/19/04.

The application has been amended as follows:

In the claims:

Claim 4 (currently amended) A substantially pure nucleic acid that hybridizes under stringent conditions to SEQ ID NO:3, wherein said stringent conditions comprise washing steps using 2X SSC, 0.1% SDS at 65° C, and wherein said nucleic acid encodes a TRELL polypeptide of SEQ ID NO:4[, or a soluble fragment thereof, that is capable of binding to a cell selected from the group consisting of:

- a) K562 promyelocytic cell;
- b) THP-I monocytic leukemia cell;
- c) an HT29 colon adenocarcinoma cell;
- d) a 293 embryonic kidney cell; and
- e) a Cos kidney fibroblast cell].

Claim 28 (currently amended) A method of expressing a TRELL polypeptide in an animal cell culture comprising the steps of:

introducing into said cell culture a vector comprising a nucleic acid molecule having consecutive nucleotides that encode said TRELL polypeptide [into said cell culture], wherein said TRELL polypeptide comprises the amino acid sequence of SEQ ID NO:4[, or a soluble fragment thereof that is capable of binding to cell selected from the group consisting of:

- a) a K562 promyelocytic cell;
- b) a THP-I monocytic leukemia cell;
- c) an HT29 colon adenocarcinoma cell;
- d) a 293 embryonic kidney cell; and
- e) a Cos kidney fibroblast cell;]

and allowing said cell culture to live under conditions wherein said nucleic acid molecule is expressed in said cell culture.

In claims 30 and 31, insert --or 49-- immediately after "claim 28".

In claim 41, delet "4" and substitute --48-- therefor.

Claim 48 (new) A substantially pure nucleic acid that hybridizes under stringent conditions to SEQ ID NO:3, wherein said stringent conditions comprise washing steps using 2X SSC and 0.1% SDS at 65° C, and wherein said nucleic acid encodes a TRELL polypeptide of SEQ ID NO:4, or a soluble fragment thereof, that is capable of binding to an HT-29 colon carcinoma cell and inducing apoptosis in said HT-29 colon carcinoma cell.

Claim 49 (new) A method of expressing a TRELL polypeptide in an animal cell culture comprising the steps of:

introducing into said cell culture a vector comprising a nucleic acid molecule having consecutive nucleotides that encode said TRELL polypeptide [into said cell culture], wherein said TRELL polypeptide comprises the amino acid sequence of SEQ ID NO:4, or a soluble fragment thereof that is capable of binding to an HT-29 colon carcinoma cell and inducing apoptosis in said HT-29 colon carcinoma cell,

and allowing said cell culture to live under conditions wherein said nucleic acid molecule is expressed in said cell culture.

REASONS FOR ALLOWANCE

The following is an examiner's statement of reasons for allowance:


The rejection of claims under 35 USC 112, first paragraph for lack of enablement is withdrawn. The specification, and the signed declaration under 35 USC 1.132 by Dr. Browning, disclose that soluble human TRELL was shown to induce apoptosis in HT29-14 cells, a well recognized tumor cell line the parent of which (HT-29) was used for many years by the National Cancer Institute as the primary tumor screen for assessing efficacy of potential therapeutics for colon cancer (see page 9 of Browning Declaration). It would be readily apparent to one of skill in the art at the time of the invention that one could use the claimed invention at least for the purpose of studying apoptosis in a tumor cell line. As such the specification enables the claimed compositions and methods. Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany

the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Any inquiry concerning this communication or earlier communications from the examiner(s) should be directed to Richard Schnizer, whose telephone number is 571-272-0762. The examiner can normally be reached Monday through Friday between the hours of 6:20 AM and 3:50 PM. The examiner is off on alternate Fridays, but is sometimes in the office anyway.

If attempts to reach the examiner by telephone are unsuccessful, the Examiner's supervisor, John Leguyader, be reached at 571-272-0760. The official central fax number is 703-872-9306. Inquiries of a general nature or relating to the status of the application should be directed to the Patent Analyst Trina Turner whose telephone number is 571-272-0564.

Richard Schnizer, Ph.D.


DAVE T. NOURSE
PRIMARY EXAMINER